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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/729,677

12/05/2003

Mark Roby

2882

3176

7590

07/27/2004

Patent Counsel
United States Surgical, a division of
TYCO HEALTHCARE GROUP LP
150 Glover Avenue
Norwalk, CT 06856

EXAMINER

SANDERS, KRIELLION ANTIONETTE

ART UNIT

PAPER NUMBER

1714

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/729,677	Applicant(s) ROBY, MARK	
	Examiner Kriellion A. Sanders	Art Unit 1714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/9/04</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1, 3-7, 9-13, 15, 17, 19, 20 and 22 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2, 4, 5, 7, 8, 15, 16 and 17 of prior U.S. Patent No. 5, 716,376. This is a double patenting rejection.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3-7, 9-13, 15, 17, 19, 20 and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Roby et al, US Patent No. 5, 716,376.

Roby et al discloses a surgical suture coating, a method of suturing a wound utilizing the coated suture and an implantable medical device coated with said surgical suture coating.

The suture coating comprises a copolymer of a predominant amount of epsilon-caprolactone and a minor amount of at least one other co-polymerizable monomer and a salt of a lactylate ester.

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The surgical suture coating comprises from 5-95% of copolymer and the remainder is fatty acid ester salt, e.g., lactylate. The surgical suture may be a braided structure and so must necessarily consist of one or more filaments. The other co-polymerizable monomer may be for example alkylene carbonate or glycolide.

Since the copolymer of a predominant amount of epsilon-caprolactone and a minor amount of at least one other co-polymerizable monomer and the salt of a lactylate ester are essentially the same as those employed by applicant, and are employed at equivalent amounts, it would have been expected that the epsilon-caprolactone and co-polymerizable monomers would produce a branched polymeric structure and that the lactylates would possess antimicrobial properties. The components are used in the same manner and quantities as employed by applicant. These properties would be inherent to the compositions.

The implantable medical device may be a clip, screw, pin, etc.

No patentable difference may be ascertained between the present and patented inventions.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roby et al as applied to claims 1, 3-7, 9-13, 15, 17, 19, 20 and 22 above, and further in view of Ogle et al, U.S. Patent No. 6,267,782 and Fischer et al, U.S. Patent No. 6,183,499.

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This rejection is particularly applicable wherein silver stearyl lactylate is additional employed.


Silver has long been recognized for its antimicrobial properties as is documented by Ogle et al. See col. 4, lines 9-43. In addition Ogle indicates the use of silver to provide antimicrobial properties to epsilon-caprolactone. See col. 6, lines 35-57. The compositions may be used as sutures and implantable devices. See col. 5, lines 39-60. Fischer et al provides more detailed description of the use of multifilament suture coated with polymers of epsilon-caprolactone and glycolide and comprising a silver antimicrobial agent. See col. 2, line 64 through col. 4, line 65. It would have been obvious to one of ordinary skill in the art to formulate a suture coating of the epsilon-caprolactone and glycolide of Roby et al, which additionally comprises a silver antimicrobial agent. Since Roby uses metal stearyl lactylates as antimicrobial agents, and silver is a known antimicrobial metal, the selection of silver stearyl lactylate as an additional antimicrobial agent in the suture coatings and resulting articles of Roby et al would have been obvious to one of ordinary skill in the art at the time of applicant's invention absent a clear showing of unexpected results attributable to the additional use of silver stearyl lactylate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kriellion A. Sanders whose telephone number is 571-272-1122. The examiner can normally be reached on Monday through Thursday 6:30-7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on 571-272-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kriellion A. Sanders
Primary Examiner
Art Unit 1714

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